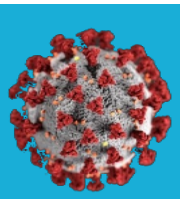
Commonwealth of Virginia
Accountability for COVID-19 Vaccine



Repositioning (Transport), Redistribution vs Transfer, and Waste

Introduction

COVID-19 vaccine products are temperature-sensitive and must be stored and handled correctly to ensure efficacy and maximize shelf life. Proper storage and handling practices are critical to minimize vaccine loss and limit risk of administering COVID-19 vaccine with reduced effectiveness.

It is expected that cold chain storage and handling requirements for COVID-19 vaccine products will vary in temperature from refrigerated (2°C to 8°C) to frozen (-15 to -25°C) to ultra-cold (-60°C to -80°C in the freezer or within the dry ice shipping container in which product was received). Ongoing stability testing may impact these requirements. Note: These temperatures are based on information available as of 2/24/2021. Updated information will be provided as it becomes available.
For a reliable cold chain, three elements must be in place:

- Well-trained staff
- Reliable storage and temperature monitoring equipment
- Accurate vaccine inventory management

The cold chain begins at the COVID-19 vaccine manufacturing plant, includes delivery to and storage at the COVID-19 vaccination provider site, and ends with administration of COVID-19 vaccine to a person. VDH and vaccination providers are responsible for maintaining vaccine quality from the time a shipment arrives at a vaccination provider site until the dose is administered.

To minimize opportunities for breaks in the cold chain, most COVID-19 vaccine will be delivered from CDC's centralized distributor directly to the location where the vaccine will be stored and administered, although some vaccine may be delivered to secondary depots for redistribution. Certain COVID-19 vaccine products, such as those with ultra-cold temperature requirements, will be shipped directly from the manufacturer to the vaccination provider site. If redistributing vaccine, providers must adhere to all cold chain requirements.

An addendum to the Vaccine Storage and Handling Toolkit that specifically addresses COVID-19 vaccines is located here: https://www.cdc.gov/vaccines/hcp/admin/storage/toolkit/index.html .

Repositioning (Transport), Redistribution, Transfer

Vaccine repositioning or transport refers to moving vaccine to a temporary vaccination site while maintaining the cold chain, for an event, after which the vaccine is returned back to its originating permanent storage location.

Redistribution refers to a planned and intentional system for sending vaccine to other enrolled COVID-19 providers, sometimes referred to as hub-and-spoke system. Transfers are unplanned and may be necessary to prevent waste, or meet an unforeseen need of enrolled COVID-19 providers.

Each of these situation require packing vaccine by personnel who are familiar with qualified pack-out materials and temperature monitors, for shipment by a third-party vendor or local movement to near-by providers while maintaining the cold chain.

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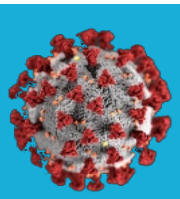

Repositioning or Transport to Satellite, Temporary, and Off-Site Clinic Storage and Handling Considerations

Satellite, temporary, or off-site clinics in collaboration with community or mobile vaccinators may assist VDH in providing equitable access for COVID-19 vaccination. However, these situations require additional oversight and enhanced storage and handling practices, including:

- The quantity of COVID-19 vaccine transported to a satellite, temporary, or off-site COVID-19 vaccination clinic should be based on the anticipated number of COVID-19 vaccine recipients and the ability of the vaccination provider to store, handle, and transport the vaccine appropriately. This is essential to minimizing the potential for vaccine wastage and spoilage.
- COVID-19 vaccines may be repositioned or transported—not shipped—to a satellite, temporary, or off-site COVID-19 vaccination clinic setting using vaccine transportation procedures outlined in the COVID-19 addendum to CDC's Vaccine Storage and Handling Toolkit. The procedures include transporting vaccines to and from the provider site at appropriate temperatures, using appropriate equipment, as well as monitoring and documenting temperatures.
- Upon arrival at the COVID-19 vaccination clinic site, vaccines must be stored correctly to maintain appropriate temperature throughout the clinic day. Temperature data must be reviewed and documented according to guidance in the COVID-19 addendum to CDC's Vaccine Storage and Handling Toolkit.
- At the end of the clinic day, temperature data must be assessed prior to returning vaccine to fixed storage units to prevent administration of vaccines that may have been compromised.
- As with all vaccines, if COVID-19 vaccines are exposed to temperature excursions *(A "temperature excursion" is an event in which the COVID-19 vaccine is exposed to temperatures outside the range(s) prescribed for storage and/or transport)* at any time, the temperature excursion should be documented and reported to the VDH Division of Immunization. The vaccines that were exposed to out-of-range temperatures must be labeled "do not use" and stored at the required temperature until further information on usability can be gathered or further instruction on disposition or recovery is received.

Redistribution/Transfer (Require documentation)

Planned redistribution of vaccines and transferring vaccine is allowed, however, with the challenge of meeting cold chain requirements for frozen or ultra-cold vaccines, VDH will be judicious in its use of redistribution and transfers, to limit it to refrigerated vaccines only.

The federally contracted vaccine distributor uses validated shipping procedures to maintain COVID-19 vaccine cold chain and minimize the likelihood of vaccine loss or damage during shipment. Once a vaccine product has been shipped to a COVID-19 vaccination provider site, the federal government will neither redistribute or transfer the product nor take financial responsibility for its redistribution or transfer.

Whenever possible, vaccine should be shipped to the location where it will be administered to minimize potential breaks in the cold chain. However, there may be circumstances where COVID-19 vaccine needs to be redistributed or transferred beyond the identified primary CDC ship-to sites (i.e., for orders smaller than the minimum order size or for large organizations whose vaccine is shipped to a central depot and requires redistribution to additional clinic locations).

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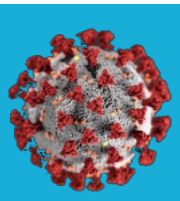

In these instances, vaccination provider organizations/facilities, third-party vendors, and other vaccination providers may be allowed, if approved by the VDH Division of Immunization, to redistribute and/or transfer COVID-19 vaccine, if validated cold-chain procedures are in place in accordance with the manufacturer's instructions and CDC's guidance on COVID-19 vaccine storage and handling.

Redistribution:
These entities must sign and agree to conditions in the CDC COVID-19 Vaccine Redistribution Agreement for the sending facility/organization and have a fully completed and signed CDC COVID-19 Vaccination Provider Profile form for each receiving location.

To redistribute COVID-19 vaccine, constituent products, and ancillary supplies to secondary sites, the organization agrees to:

1. Sign and comply with all conditions as outlined in the CDC COVID-19 Vaccination Program Provider Agreement.
2. Ensure secondary locations receiving redistributed COVID-19 vaccine, constituent products, or ancillary supplies also sign and comply with all conditions in the CDC COVID-19 Vaccination Program Provider Agreement.
3. Comply with vaccine manufacturer instructions on cold chain management and CDC guidance in CDC's Vaccine Storage and Handling Toolkit, which has been updated to include specific information related to COVID-19 vaccine, for any redistribution of COVID-19 vaccine to secondary locations.
4. Document and make available any records of COVID-19 vaccine redistribution to secondary sites to jurisdiction's immunization program as requested, including dates and times of redistribution, sending and receiving locations, lot numbers, expiration dates, and numbers of doses.

Organizations planning for redistribution of COVID-19 vaccine must carefully assess the associated risks and costs (e.g., vaccine loss due to temperature excursions, purchase of vaccine-specific portable refrigerators and/or containers) before planning this activity.

Provider agreement, profile form, and redistribution agreement (if applicable) must be thoroughly and accurately completed and retained on file for a minimum of 3 years, and made available to CDC upon request. Please check here for additional information: https://www.vdh.virginia.gov/immunization/covid19vaccine/.

Transfer:
Since transfers are unplanned, a redistribution agreement is not required but it must be reported using the REDCap survey located on the DOI COVID website. This will facilitate vaccine accountability and ensure continuity of vaccine supply. The site transferring the vaccine must ensure the recipient site is an enrolled COVID-19 provider, AND ensure the vaccine cold chain is preserved.

NOTE: CDC does not pay for or reimburse jurisdictions, COVID-19 vaccination provider organizations, facilities, or other entities for any redistribution beyond the initial designated primary CDC ship-to location, or for any vaccine-specific portable refrigerators and/or qualified containers and pack-outs.

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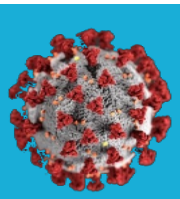

Waste/Recovery (Returning Federal Vaccine)/Excursions

Waste:
Appropriately plan for the number of vaccines needed so that none is wasted. VDH advises vaccination clinics to create standby lists of prioritized persons to receive any unused doses and call individuals on the list if there are extra doses.

On February 16th Pfizer vaccine vials began being distributed as 6 doses/vial, instead of 5 doses/vial. Some providers may experience a situation when a 6th dose cannot be drawn. When this happens the dose should be reported as waste for vaccine accountability purposes.

Use the "**COVID19 Wastage Report Form**" available on the VDH Vaccine Webpage for Healthcare Providers to report wasted vaccine.

Recovery:
COVID-19 vaccine recovery is a system for collecting vaccine that will not be administered. Details of COVID-19 vaccine recovery are still being finalized and will be communicated when available. Until these details are known providers are encouraged to dispose of COVID vaccine waste in accordance with local regulations.

Vaccine is fragile and can be damaged in many ways. It might be damaged in transport or a vial might break. Vaccine might be exposed to temperature excursions due to loss of power or a malfunctioning storage unit. Hazardous situations require disposing of vaccine in biohazardous waste. Broken vials and syringes that were drawn up and not administered are considered hazardous and cannot be recovered. Vaccine vials that have been punctured cannot be recovered. Vaccine doses that cannot be recovered should be documented for vaccine accountability purposes.

Excursions:
As with all vaccines, if COVID-19 vaccines are exposed to temperature excursions (A "temperature excursion" is an event in which the COVID-19 vaccine is exposed to temperatures outside the range(s) prescribed for storage and/or transport) at any time, the temperature excursion should be documented and reported to the VDH Division of Immunization. The vaccines that were exposed to out-of-range temperatures must be labeled "do not use" and stored at the required temperature until further information on usability can be gathered or further instruction on disposition or recovery is received. Vaccine that is non-viable according to stability data can be removed from storage and staged for recovery. COVID-19 vaccine that expires will need to be recovered. If/when a vaccination provider site has completed immunization activities with COVID-19 vaccine, appropriate storage of the vaccine must be maintained until it has expired or recovery guidance is issued stating otherwise.